amended claim language is fully supported by the specification and original claims. For example, support for unit dosage forms comprising a "container" is found in U.S. Patent 6,096,331 (see col. 20, line 65 to col. 21, line 8) which is incorporated into the present specification in its entirety. Claims 1-171 are pending.

The objection to the specification under 37 C.F.R. 1.75(d)(1), as allegedly failing to provide proper antecedent basis for the claimed subject matter, is respectfully traversed. Applicants respectfully disagree with the Examiner's assertion that antecedent basis allegedly does not exist for the term "docetaxel". In contrast to the Examiner's assertion, it is respectfully submitted that proper antecedent basis exists for the term "docetaxel" based on previous reference to the term "Taxotere". Indeed, the term "Taxotere" appears throughout U.S. Patent No. 5,916,596 (see, e.g., col. 5, line 11, col. 12, line 10) which is incorporated by reference into the present specification in its entirety. Those skilled in the art readily recognize that the terms "docetaxel" and "Taxotere" refer to the same compound. Indeed, just as paclitaxel is marketed as "Taxol", docetaxel is marketed as "Taxotere".

Moreover, those skilled in the art readily recognize that docetaxel is merely an analog of paclitaxel. It is made abundantly clear in the present specification that antineoplastic analogs of paclitaxel, such as docetaxel, are contemplated for use in the practice of the present invention (see, for example, specification, page 11, line 22; page 14, line 32 to page 15, line 4; and page 18, line 6). Thus, antecedent basis for "docetaxel" clearly exists in the present specification. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

The rejection of claims 1-171 under the judicially created doctrine of double patenting over claims 1-57 of U.S. Patent 6,096,331 is acknowledged. The provisional rejection of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122, 125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, 164-166, 168, and 170 under the judicially created doctrine of double patenting over claims 1-78 of co-pending Application No. 09/628,389 is also

acknowledged. These rejections will be addressed after the claims are otherwise in condition for allowance (e.g., by filing a terminal disclaimer or other such action as deemed appropriate).

The rejection of claims 1-171 under 35 U.S.C. 112, first paragraph is respectfully traversed. Applicants respectfully disagree with the Examiner's assertion (see Office Action mailed January 30, 2001, page 4, lines 7-12) that the present specification, while being enabling for dissolved biologic enclosed within a polymeric shell, allegedly does not provide enablement for a unit dosage form comprising a vessel.

In applying the rejection under 35 U.S.C. 112, first paragraph, it is respectfully submitted that the Examiner has misinterpreted claims 1-171. Specifically, it appears that the Examiner has construed the terms "unit dosage form" and "vessel" in a manner inconsistent with the generally accepted definitions of these terms, and in a manner inconsistent with the use of these terms in the present specification (see, for example, page 26, line 29 to page 27, line 5). Those skilled in the art readily understand that a "unit dosage form" is an article of manufacture comprising a vessel which contains therein a specified amount of a therapeutically active agent. As such, those skilled in the art will understand the term "vessel", as used in conjunction with the phrase "unit dosage form", to refer to the physical container (such as, for example, a jar, a bottle, a vial, and the like) in which the therapeutically active agent is packaged. Thus, Applicants respectfully submit that a "vessel", as consistently used throughout the claims, is not a polymeric shell. Accordingly, the Examiner's assertion that the specification does not teach a unit dosage form comprising a vessel wherein the vessel is not a polymeric shell is respectfully submitted to be irrelevant.

However, to reduce the issues and expedite prosecution, claims 1, 17, 30, 45, 58-70, 79-91, 98, 102, 104, 108, 110, 114, 116, 120, 122, 126, 137, 142, 156, 159, 160, and 163-171 have been amended, replacing the term "vessel" with the term "container" to illustrate with greater particularity that this component of the unit dosage form is a physical container, and not a polymeric shell. It is respectfully submitted that those skilled in the art could readily produce a

unit dosage form according to the present invention based on the teachings of the present specification. Clearly, undue experimentation would not be required to manufacture a physical container having a specified amount of taxane contained therein. Indeed, the manufacture of unit dosage forms merely involves routine packaging steps which are well known to those skilled in the art. Accordingly, Applicants respectfully submit that the rejection under 35 U.S.C. 112, first paragraph, does not apply to amended claims 1, 17, 30, 45, 58-70, 79-91, 98, 102, 104, 108, 110, 114, 116, 120, 122, 126, 137, 142, 156, 159, 160, and 163-171 and claims dependent therefrom.

The rejection of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, 164-166, 168, and 170 under 35 U.S.C. 102(b) as allegedly being anticipated by *Drug Facts and Comparisons* (page 3553), is respectfully traversed. Applicants' invention, as defined for example by claim 1, distinguishes over this reference by requiring unit dosage forms comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about three hours. In contrast, *Drug Facts and Comparisons* is silent with respect to unit dosage forms. Indeed, this reference does not describe single doses (i.e., unit dosage forms) containing taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2. Instead, the disclosure in *Drug Facts and Comparisons* merely describes the recommended quantity of paclitaxel to be administered to a subject over an extended administration period as determined by the FDA in 1992.

Moreover, those skilled in the art readily recognize that unit dosage forms comprising taxane in the range contemplated by the present claims were not available as of December 1992. Thus, the FDA recommended dosage set forth in *Drug Facts and Comparisons* (i.e., 135 mg/m^2 to 175 mg/m^2) could not be administered in a single dose (i.e., unit dosage form), as required by the present claims. Clearly, only the present invention contemplates unit dosage forms comprising taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2. Thus, the rejection of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, 164-166, 168, and 170 under 35 U.S.C. 102(b) is

not properly applied. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

The rejection of claims 17-29, 45-57, 79-97, 102, 103, 108, 109, 114, 115, 120, 121, 126, 127, 132, 136, 142-144, 148, 152, 159, 163, 167, 169, and 171 under 35 U.S.C. 102(b) as allegedly being anticipated by *Drug Facts and Comparisons* (page 3558), is respectfully traversed. Applicants' invention, as defined for example by claim 17, distinguishes over this reference by requiring unit dosage forms comprising a container containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over an administration period no greater than about three hours. In contrast, *Drug Facts and Comparisons* is silent with respect to unit dosage forms. Indeed, this reference does not describe single doses (i.e., unit dosage forms) containing docetaxel in the range of about 40 mg/m^2 to about 800 mg/m^2. Instead, the disclosure in *Drug Facts and Comparisons* merely describes the recommended quantity of paclitaxel to be administered to a subject over an extended administration period as determined by the FDA in 1996.

Moreover, those skilled in the art readily recognize that unit dosage forms comprising docetaxel in the range contemplated by the present claims were not available in 1996. Thus, the FDA recommended dosage set forth in *Drug Facts and Comparisons* (i.e., 60 mg/m^2 to 100 mg/m^2) could not be administered in a single dose (i.e., unit dosage form), as required by the present claims. Clearly, only the present invention contemplates unit dosage forms comprising docetaxel in the range of about 40 mg/m^2 to about 800 mg/m^2. Thus, the rejection of claims 17-29, 45-57, 79-97, 102, 103, 108, 109, 114, 115, 120, 121, 126, 127, 132, 136, 142-144, 148, 152, 159, 163, 167, 169, and 171 under 35 U.S.C. 102(b) is not properly applied. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

The rejection of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, and 137-141 under 35 U.S.C. 102(b) as allegedly being anticipated by Boni,

et. al. (U.S. 5,683,715) is respectfully traversed. Applicants' invention, as defined for example by claim 1, distinguishes over Boni by requiring unit dosage forms comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about three hours. In contrast, Boni does not contemplate unit dosage forms comprising taxane. Indeed, Boni is silent with respect to single dosages (i.e., unit dosage forms) comprising taxane. In addition, Boni does not contemplate administration protocols required by the present invention. Thus, the rejection of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, and 137-141 under 35 U.S.C. 102(e) is not properly applied. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

The rejection of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, 137-141, 145-147, 149-151, 153, 154, 156-158, 160-162, 164-168, and 170 under 35 U.S.C. 102(b) as allegedly being anticipated by Rahman, et. al. (U.S. 5,648,090) is respectfully traversed. Applicants' invention, as defined for example by claim 1, distinguishes over Rahman by requiring unit dosage forms comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about three hours. In contrast, Rahman does not contemplate unit dosage forms comprising taxane. Indeed, Rahman is silent with respect to single dosages (i.e., unit dosage forms) comprising taxane. Clearly, only the present invention contemplates unit dosage forms containing taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2.

In addition, Rahman does not disclose the administration protocols required by the present invention. Instead, as acknowledged by the Examiner (see Office Action mailed January 30, 2001, page 8, line 1) Rahman merely teaches that taxol formulations are generally administered intravenously. Thus, the Examiner's assertion (see Office Action mailed January 30, 2001, page 8, lines 2-4) that Rahman allegedly anticipates the present claims because Rahman allegedly teaches the composition, method of treatment, and method of administration

of the present claims is respectfully submitted to be in error. Accordingly, reconsideration and withdrawal of the rejection of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, 137-141, 145-147, 149-151, 153, 154, 156-158, 160-162, 164-168, and 170 under 35 U.S.C. 102(e) are respectfully requested.

The rejection of claims 1-171 under 35 U.S.C. 103(a) as allegedly being unpatentable over *Drug Facts and Comparisons* (page 3553 or page 3558) is respectfully traversed. Applicants' invention, as defined for example by claim 1, distinguishes over this reference by requiring unit dosage forms comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about three hours. In contrast, *Drug Facts and Comparisons* is silent with respect to unit dosage forms.

In addition, Applicants respectfully submit that the disclosure on either page 3553 or page 3558 of *Drug Facts and Comparisons* does not fairly suggest the unit dosage forms required by, for example, claim 1. Based only on this disclosure, those skilled in the art would not be motivated to produce a unit dosage form as required by claim 1. Instead, as acknowledged by the Examiner (see Office Action mailed January 30, 2001, page 8, lines 11-14), those skilled in the art may be motivated to produce a pharmaceutical formulation of taxane. However, a pharmaceutical formulation and a unit dosage form are clearly not one and the same. It is readily apparent that the Examiner has used hindsight based on the present specification in asserting *Drug Facts and Comparisons* against the present claims. Such use of Applicants' specification is clearly improper. Thus, it is respectfully submitted that the rejection under 35 U.S.C. 103(a) is not properly applied. Accordingly, reconsideration and withdrawal of the rejection of claims 1-171 are respectfully requested.

The rejection of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, 137-141, 145-147, 149-151, 153, 154, 156-158, 160-162, 164-168, and 170 under 35 U.S.C. 103(a) as allegedly being unpatentable over Boni or Rahman is respectfully

traversed. Applicants' invention, as defined for example by claim 1, distinguishes over either Boni or Rahman, taken alone or in combination, by requiring unit dosage forms comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about three hours. In contrast, neither Boni nor Rahman contemplates unit dosage forms comprising taxane. Indeed, Boni and Rahman are silent with respect to single dosages (i.e., unit dosage forms) comprising taxane. In addition, Boni and Rahman do not contemplate administration protocols required by the present invention.

In addition, it is respectfully submitted that neither Boni nor Rahman suggest the unit dosage forms required by, for example, claim 1. Based only on these references, those skilled in the art would not be motivated to produce single doses (i.e., unit dosage forms) of taxane as required by the present claims. Indeed, only the present invention contemplates unit dosage forms containing in the range of about 30 mg/m^2 to about 1000 mg/m^2 of taxane.

Furthermore, Applicants respectfully disagree with the Examiner's assertions (see Office Action mailed January 30, 2001, page 9, lines 5-7 and 18-20) that based on either Boni's or Rahman's teaching, the presently claimed administration protocols would allegedly be obvious to those skilled in the art. Indeed, it is well known that determining an optimum dosage level of taxane, i.e., achieving maximum efficacy while minimizing toxicity, is a notoriously difficult and unpredictable task. In contrast to the Examiner's assertions, there is clearly no suggestion in either Boni or Rahman that the dosages and treatment protocols contemplated by the present invention could be carried out safely while providing maximum therapeutic benefit. Clearly, only the present invention illustrates that the presently claimed dosages can be administered to achieve maximum efficacy while minimizing toxicity. Thus, it is respectfully submitted that the rejection of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, 137-141, 145-147, 149-151, 153, 154, 156-158, 160-162, 164-168, and 170 under 35 U.S.C. 103(a) over Boni or Rahman is not properly applied. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

The rejection of claims 1-171 under 35 U.S.C. 103(a) as allegedly being unpatentable over Boni, or Rahman in view of Li, et. al., (U.S. 5,977,163) is respectfully traversed. Applicants' invention, as defined for example by claim 1, distinguishes over Boni and Rahman by requiring unit dosage forms comprising a container containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about three hours. In contrast, neither Boni nor Rahman contemplates unit dosage forms comprising taxane. Indeed, Boni and Rahman are silent with respect to single dosages (i.e., unit dosage forms) comprising taxane. In addition, Boni and Rahman do not contemplate administration protocols required by the present invention.

Reliance on Li fails to cure the deficiencies of Boni and Rahman. As acknowledged by the Examiner (see Office Action mailed January 30, 2001, page 10, lines 9-12), Li merely discloses that docetaxel and paclitaxel are anticancer agents. Similar to Boni and Rahman, Li is silent with respect to unit dosage forms comprising taxanes.

Moreover, it is respectfully submitted that there is no motivation to combine Li with Boni and/or Rahman, absent the teachings of the present invention. The Examiner's assertion (see Office Action mailed January 30, 2001, page 10, lines 12-14) that one skilled in the art would have been motivated to use any well known antitumor agent (such as docetaxel) in the formulations disclosed in Boni and/or Rahman is respectfully submitted to be irrelevant. The present invention is drawn to unit dosage forms comprising taxanes, formulations thereof, and methods for use thereof, which allow systemic administration to a human subject in need thereof at doses and over administration periods and/or treatment cycles not previously possible. In contrast, Li merely discloses that docetaxel is an effective anticancer agent. Clearly, those skilled in the art could not arrive at the present invention by practicing the combined teachings of Boni, Rahman, and Li. Thus, it appears the Examiner has used hindsight based on the present specification in combining Li with Boni and/or Rahman. Such use of Applicants' specification

is clearly improper. Accordingly, reconsideration and withdrawal of the rejection of claims 1-171 under 35 U.S.C. 103(a) are respectfully requested.

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. If any matters remain to be resolved in view of this communication, the Examiner is invited to contact the undersigned at the telephone number set forth below so that a prompt disposition of this application can be achieved.

Respectfully submitted,

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Enclosure: Appendix

APPENDIX

This application is a divisional application of U.S. Serial No. 08/926,155, filed September 9, 1997, now issued as U.S. Patent No. 6,096,331, which is a continuation-in-part of U.S. Serial No. 08/720,756, filed October 1, 1996, now issued as U.S. Patent 5,916,596, and **[is a continuation-in-part of]** U.S. Serial No. 08/485,448, filed June 7, 1995, **[now pending]** now issued as U.S. Patent No. 5,665,382, which is, in turn, a continuation-in-part of U.S. Serial No. 08/200,235, filed February 22, 1994, now issued as U.S. Patent No. 5,498,421, which is, in turn, a continuation-in-part of U.S. Serial No. 08/023,698, filed February 22, 1993, now issued as U.S. Patent No. 5,439,686, and U.S. Serial No. 08/035,150, filed March 26, 1993, now issued as U.S. Patent No. 5,362,478, the contents of each of which are hereby incorporated by reference in their entirety.

1. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of taxane to provide for administration to a subject **[at]** a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about 3 hours.

2. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 80 mg/m^2 to about 700 mg/m^2.

3. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 50 mg/m^2 to about 800 mg/m^2.

4. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 50 mg/m^2 to about 800 mg/m^2.

5. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 60 mg/m^2 to about 400 mg/m^2.

6. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 65 mg/m^2 to about 400 mg/m^2.

7. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

8. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 85 mg/m^2 to about 375 mg/m^2.

9. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 100 mg/m^2 to about 300 mg/m^2.

10. (Reiterated) A unit dosage form according to claim 1, wherein said subject is human.

11. (Reiterated) A unit dosage form according to claim 1, wherein the cycle time between administrations of said total dose is less than about three weeks.

12. (Reiterated) A unit dosage form according to claim 1, wherein said taxane is administered locally.

13. (Reiterated) A unit dosage form according to claim 1, wherein said taxane is administered systemically.

14. (Reiterated) A unit dosage form according to claim 1, wherein said taxane is in a non-aqueous formulation.

15. (Reiterated) A unit dosage form according to claim 1, wherein said taxane is paclitaxel.

16. (Reiterated) A unit dosage form according to claim 1, wherein said taxane a paclitaxel analog.

17. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of docetaxel to provide for administration to a subject **[at]** a total dose of docetaxel in the

range of about 40 mg/m^2 to about 800 mg/m^2 over an administration period no greater than about 3 hours.

18. (Reiterated) A unit dosage form according to claim 17, wherein said total dose is in the range of about 50 mg/m^2 to about 800 mg/m^2.

19. (Reiterated) A unit dosage form according to claim 17, wherein said total dose is in the range of about 60 mg/m^2 to about 400 mg/m^2.

20. (Reiterated) A unit dosage form according to claim 17, wherein said total dose is in the range of about 65 mg/m^2 to about 400 mg/m^2.

21. (Reiterated) A unit dosage form according to claim 17, wherein said total dose is in the range of about 80 mg/m^2 to about 700 mg/m^2.

22. (Reiterated) A unit dosage form according to claim 17, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

23. (Reiterated) A unit dosage form according to claim 17, wherein said total dose is in the range of about 85 mg/m^2 to about 375 mg/m^2.

24. (Reiterated) A unit dosage form according to claim 17, wherein said total dose is in the range of about 100 mg/m^2 to about 300 mg/m^2.

25. (Reiterated) A unit dosage form according to claim 17, wherein said subject is human.

26. (Reiterated) A unit dosage form according to claim 17, wherein the cycle time between administrations of said total dose is less than about three weeks.

27. (Reiterated) A unit dosage form according to claim 17, wherein said docetaxel is administered locally.

28. (Reiterated) A unit dosage form according to claim 17, wherein said docetaxel is administered systemically.

29. (Reiterated) A unit dosage form according to claim 17, wherein said docetaxel is in a non-aqueous formulation.

30. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of taxane to provide for administration to a subject **[at]** a total dose of taxane in the range of about 40 mg/m^2 to about 800 mg/m^2 with a cycle time of no greater than about three weeks between administrations of said total dose.

31. (Reiterated) A unit dosage form according to claim 30, wherein said total dose is in the range of about 80 mg/m^2 to about 700 mg/m^2.

32. (Reiterated) A unit dosage form according to claim 30, wherein said total dose is in the range of about 50 mg/m^2 to about 800 mg/m^2.

33. (Reiterated) A unit dosage form according to claim 30, wherein said total dose is in the range of about 60 mg/m^2 to about 400 mg/m^2.

34. (Reiterated) A unit dosage form according to claim 30, wherein said total dose is in the range of about 65 mg/m^2 to about 400 mg/m^2.

35. (Reiterated) A unit dosage form according to claim 30, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

36. (Reiterated) A unit dosage form according to claim 30, wherein said total dose is in the range of about 85 mg/m^2 to about 375 mg/m^2.

37. (Reiterated) A unit dosage form according to claim 30, wherein said total dose is in the range of about 100 mg/m^2 to about 300 mg/m^2.

38. (Reiterated) A unit dosage form according to claim 30, wherein said subject is human.

39. (Reiterated) A unit dosage form according to claim 30, wherein said taxane is administered locally.

40. (Reiterated) A unit dosage form according to claim 30, wherein said taxane is administered systemically.

41. (Reiterated) A unit dosage form according to claim 30, wherein said taxane is in a non-aqueous formulation.

42. (Reiterated) A unit dosage form according to claim 30, wherein said taxane is in a formulation containing less than about 10% ethanol.

43. (Reiterated) A unit dosage form according to claim 30, wherein said taxane is paclitaxel.

44. (Reiterated) A unit dosage form according to claim 30, wherein said taxane a paclitaxel analog.

45. (Amended)A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of docetaxel to provide for administration to a subject **[at]** a total dose of docetaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 with a cycle time of no greater than about three weeks between administrations of said total dose.

46. (Reiterated) A unit dosage form according to claim 45, wherein said total dose is in the range of about 50 mg/m^2 to about 800 mg/m^2.

47. (Reiterated) A unit dosage form according to claim 45, wherein said total dose is in the range of about 60 mg/m^2 to about 400 mg/m^2.

48. (Reiterated) A unit dosage form according to claim 45, wherein said total dose is in the range of about 65 mg/m^2 to about 400 mg/m^2.

49. (Reiterated) A unit dosage form according to claim 45, wherein said total dose is in the range of about 80 mg/m^2 to about 700 mg/m^2.

50. (Reiterated) A unit dosage form according to claim 45, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

51. (Reiterated) A unit dosage form according to claim 45, wherein said total dose is in the range of about 85 mg/m^2 to about 375 mg/m^2.

52. (Reiterated) A unit dosage form according to claim 45, wherein said total dose is in the range of about 100 mg/m^2 to about 300 mg/m^2.

53. (Reiterated) A unit dosage form according to claim 45, wherein said subject is human.

54. (Reiterated) A unit dosage form according to claim 45, wherein said docetaxel is administered locally.

55. (Reiterated) A unit dosage form according to claim 45, wherein said docetaxel is administered systemically.

56. (Reiterated) A unit dosage form according to claim 45, wherein said docetaxel is in a non-aqueous formulation.

57. (Reiterated) A unit dosage form according to claim 45, wherein said docetaxel is in a formulation containing less than about 10% ethanol.

58. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of taxane to provide for administration to a subject **[at]** a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said **[vessel]** container comprises in the range of about 4 mg to about 822 mg of said taxane.

59. (Amended) A unit dosage form according to claim 58, wherein said **[vessel]** container comprises in the range of about 4 mg to about 13 mg of said taxane.

60. (Amended) A unit dosage form according to claim 58, wherein said **[vessel]** container comprises in the range of about 13 mg to about 30 mg of said taxane.

61. (Amended) A unit dosage form according to claim 58, wherein said **[vessel]** container comprises in the range of about 20 mg to about 69 mg of said taxane.

62. (Amended) A unit dosage form according to claim 58, wherein said **[vessel]** container comprises in the range of about 45 mg to about 69 mg of said taxane.

63. (Amended) A unit dosage form according to claim 58, wherein said **[vessel]** container comprises in the range of about 69 mg to about 90 mg of said taxane.

64. (Amended) A unit dosage form according to claim 58, wherein said **[vessel]** container comprises in the range of about 69 mg to about 103 mg of said taxane.

65. (Amended) A unit dosage form according to claim 58, wherein said **[vessel]** container comprises in the range of about 103 mg to about 120 mg of said taxane.

66. (Amended) A unit dosage form according to claim 58, wherein said **[vessel]** container comprises in the range of about 103 mg to about 148 mg of said taxane.

67. (Amended) A unit dosage form according to claim 58, wherein said **[vessel]** container comprises in the range of about 120 mg to about 367 mg of said taxane.

68. (Amended) A unit dosage form according to claim 58, wherein said **[vessel]** container comprises in the range of about 148.1 mg to about 367 mg of said taxane.

69. (Amended) A unit dosage form according to claim 58, wherein said **[vessel]** container comprises in the range of about 367 mg to about 548 mg of said taxane.

70. (Amended) A unit dosage form according to claim 58, wherein said **[vessel]** container comprises in the range of about 367 mg to about 822 mg of said taxane.

71. (Reiterated) A unit dosage form according to claim 58, wherein the administration period for delivering said total dose is no greater than about 3 hours.

72. (Reiterated) A unit dosage form according to claim 58, wherein the cycle time between administrations of said taxane is less than about three weeks.

73. (Reiterated) A unit dosage form according to claim 58, wherein said subject is human.

74. (Reiterated) A unit dosage form according to claim 58, wherein said taxane is administered locally.

75. (Reiterated) A unit dosage form according to claim 58, wherein said taxane is administered systemically.

76. (Reiterated) A unit dosage form according to claim 58, wherein said taxane is in a non-aqueous formulation.

77. (Reiterated) A unit dosage form according to claim 58, wherein said taxane is paclitaxel.

78. (Reiterated) A unit dosage form according to claim 58, wherein said taxane is a paclitaxel analog.

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79. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of docetaxel to provide for administration to a subject **[at]** a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said **[vessel]** container comprises a unit dose in the range of about 4 mg to about 822 mg of said docetaxel.

80. (Amended) A unit dosage form according to claim 79, wherein said **[vessel]** container comprises in the range of about 4 mg to about 13 mg of said docetaxel.

81. (Amended) A unit dosage form according to claim 79, wherein said **[vessel]** container comprises in the range of about 13 mg to about 30 mg of said docetaxel.

82. (Amended) A unit dosage form according to claim 79, wherein said **[vessel]** container comprises in the range of about 20 mg to about 69 mg of said docetaxel.

83. (Amended) A unit dosage form according to claim 79, wherein said **[vessel]** container comprises in the range of about 45 mg to about 69 mg of said docetaxel.

84. (Amended) A unit dosage form according to claim 79, wherein said **[vessel]** container comprises in the range of about 69 mg to about 90 mg of said docetaxel.

85. (Amended) A unit dosage form according to claim 79, wherein said **[vessel]** container comprises in the range of about 69 mg to about 103 mg of said docetaxel.

86. (Amended) A unit dosage form according to claim 79, wherein said **[vessel]** container comprises in the range of about 103 mg to about 120 mg of said docetaxel.

87. (Amended) A unit dosage form according to claim 79, wherein said **[vessel]** container comprises in the range of about 103 mg to about 148 mg of said docetaxel.

88. (Amended) A unit dosage form according to claim 79, wherein said **[vessel]** container comprises in the range of about 120 mg to about 367 mg of said docetaxel.

89. (Amended) A unit dosage form according to claim 79, wherein said **[vessel]** container comprises in the range of about 148 mg to about 367 mg of said docetaxel.

90. (Amended) A unit dosage form according to claim 79, wherein said **[vessel]** container comprises in the range of about 367 mg to about 548 mg of said docetaxel.

91. (Amended) A unit dosage form according to claim 79, wherein said **[vessel]** container comprises in the range of about 367 mg to about 822 mg of said docetaxel.

92. (Reiterated) A unit dosage form according to claim 79, wherein the administration period for delivering said docetaxel is no greater than about 3 hours.

93. (Reiterated) A unit dosage form according, to claim 79, wherein the cycle time between administrations of said total dose is less than about three weeks.

94. (Reiterated) A unit dosage form according, to claim 79, wherein said subject is human.

95. (Reiterated) A unit dosage form according, to claim 79, wherein said docetaxel is administered locally.

96. (Reiterated) A unit dosage form according, to claim 79, wherein said docetaxel is administered systemically.

97. (Reiterated) A unit dosage form according to claim 79, wherein said docetaxel is in a non-aqueous formulation.

98. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of taxane to provide for administration to a subject **[at]** a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said taxane remains stable for greater than about 24 hours and less than about 3 days following addition thereto of an aqueous diluent.

99. (Reiterated) A unit dosage form according to claim 98, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

100. (Reiterated) A unit dosage form according to claim 98, wherein said taxane is paclitaxel.

101. (Reiterated) A unit dosage form according to claim 98, wherein said taxane is a paclitaxel analog.

102. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of docetaxel to provide for administration to a subject **[at]** a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said docetaxel remains stable for greater than about 24 hours and less than about 3 days following addition thereto of an aqueous diluent.

103. (Reiterated) A unit dosage form according to claim 102, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

104. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of taxane to provide for administration to a subject **[at]** a total dose of taxane in the range

of about 30 mg/m^2 to about 1000 mg/m^2, wherein refrigeration does not adversely affect the stability of said taxane.

105. (Reiterated) A unit dosage form according to claim 104, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

106. (Reiterated) A unit dosage form according to claim 104, wherein said taxane is paclitaxel.

107. (Reiterated) A unit dosage form according to claim 104, wherein said taxane is a paclitaxel analog.

108. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of docetaxel to provide for administration to a subject **[at]** a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein refrigeration does not adversely affect the stability of said docetaxel.

109. (Reiterated) A unit dosage form according to claim 108, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

110. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of taxane to provide for administration to a subject **[at]** a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form is useful for the treatment of primary tumors.

111. (Reiterated) A unit dosage form according to claim 110, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

112. (Reiterated) A unit dosage form according to claim 110, wherein said taxane is paclitaxel.

113. (Reiterated) A unit dosage form according to claim 110, wherein said taxane is a paclitaxel analog.

114. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of docetaxel to provide for administration to a subject **[at]** a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form is useful for the treatment of primary tumors.

115. (Reiterated) A unit dosage form according to claim 114, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

116. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of taxane to provide for administration to a subject **[at]** a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form is useful for the treatment of metastatic tumors.

117. (Reiterated) A unit dosage form according to claim 116, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

118. (Reiterated) A unit dosage form according to claim 116, wherein said taxane is paclitaxel.

119. (Reiterated) A unit dosage form according to claim 116, wherein said taxane is a paclitaxel analog.

120. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of docetaxel to provide for administration to a subject **[at]** a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form is useful for the treatment of metastatic tumors.

121. (Reiterated) A unit dosage form according to claim 120, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

122. (Amended) A unit dosage form comprising a **[vessel]** container containing a quantity of a formulation of taxane sufficient to provide for administration to a subject **[at]** a total dose of

taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said formulation does not leach plasticizer from administration devices used to administer said unit dosage formulation.

123. (Reiterated) A unit dosage form according to claim 122, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

124. (Reiterated) A unit dosage form according to claim 122, wherein said taxane is paclitaxel.

125. (Reiterated) A unit dosage form according to claim 122, wherein said taxane is a paclitaxel analog.

126. (Amended) A unit dosage form comprising a **[vessel]** container containing a quantity of a formulation of docetaxel sufficient to provide for administration to a subject **[at]** a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said formulation does not leach plasticizer from administration devices used to administer said unit dosage formulation.

127. (Reiterated) A unit dosage form according to claim 126, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

128. (Reiterated) A taxane containing formulation suitable for the delivery of a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, with an administration period of no greater than about 3 hours.

129. (Reiterated) A formulation according to claim 128, wherein said total dose of taxane is in the range of about 80 mg/m^2 to about 700 mg/m^2.

130. (Reiterated) A formulation according to claim 128, wherein said taxane is paclitaxel.

131. (Reiterated) A formulation according to claim 128, wherein said taxane is a paclitaxel analog.

132. (Reiterated) A docetaxel containing formulation suitable for the delivery of a total dose of docetaxel in the range of about 80 mg/m^2 to about 700 mg/m^2, with an administration period of no greater than about 3 hours.

133. (Reiterated) A taxane containing formulation suitable for the delivery of a total dose of taxane in the range of about 80 mg/m^2 to about 700 mg/m^2, with a treatment cycle of no greater than about 3 weeks.

134. (Reiterated) A formulation according to claim 133, wherein said taxane is paclitaxel.

135. (Reiterated) A formulation according to claim 133, wherein said taxane is a paclitaxel analog.

136. (Reiterated) A docetaxel containing formulation suitable for the delivery of a total dose of docetaxel in the range of about 80 mg/m^2 to about 700 mg/m^2, with a treatment cycle of no greater than about 3 weeks.

137. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of taxane to allow systemic administration to a subject, employing a standard intravenous infusion set, of a total dose in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane.

138. (Reiterated) A unit dosage form according to claim 137, wherein said infusion set is polyolefin.

139. (Reiterated) A unit dosage form according to claim 138, wherein said polyolefin is polyethylene.

140. (Reiterated) A unit dosage form according to claim 137, wherein said taxane is paclitaxel.

141. (Reiterated) A unit dosage form according to claim 137, wherein said taxane is a paclitaxel analog.

142. (Amended) A unit dosage form comprising a **[vessel]** container containing a sufficient quantity of docetaxel to allow systemic administration to a subject, employing a standard intravenous infusion set, of a total dose in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said docetaxel.

143. (Reiterated) A unit dosage form according to claim 142, wherein said infusion set is polyolefin.

144. (Reiterated) A unit dosage form according to claim 143, wherein said polyolefin is polyethylene.

145. (Reiterated) A method for administration of taxane to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane to said subject in a pharmaceutically acceptable formulation with a treatment cycle no greater than about 3 weeks.

146. (Reiterated) A method according to claim 145, wherein said taxane is paclitaxel.

147. (Reiterated) A method according to claim 145, wherein said taxane is a paclitaxel analog.

148. (Reiterated) A method for administration of docetaxel to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said docetaxel to said subject in a pharmaceutically acceptable formulation with a treatment cycle no greater than about 3 weeks.

149. (Reiterated) A method for administration of taxane to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane to said subject in a pharmaceutically acceptable formulation with an administration period no greater than about 3 hours.

150. (Reiterated) A method according to claim 149, wherein said taxane is paclitaxel.

151. (Reiterated) A method according to claim 149, wherein said taxane is a paclitaxel analog.

152. (Reiterated) A method for administration of docetaxel to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said docetaxel to said subject in a pharmaceutically acceptable formulation with an administration period no greater than about 3 hours.

153. (Reiterated) A method for administration of taxane to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane to said subject in a pharmaceutically acceptable formulation, wherein the treatment of said subject receiving said taxane does not include the administration of agents which aid in the recovery from hematologic toxicity.

154. (Reiterated) A method according to claim 153, wherein said agent is a cytokine.

155. (Reiterated) A method for administration of docetaxel to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said docetaxel to said subject in a pharmaceutically acceptable formulation, wherein the treatment of said subject receiving said docetaxel does not include the administration of cytokines.

156. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[vessel]** container containing a sufficient quantity of taxane to provide for administration to a subject **[at]** a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said taxane remains stable for greater than about 24 hours and less than about 3 days following addition thereto of an aqueous diluent.

157. (Reiterated) A method according to claim 156, wherein said taxane is paclitaxel.

158. (Reiterated) A method according to claim 156, wherein said taxane is a paclitaxel analog.

159. (Amended) A method for administration of docetaxel to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[vessel]** container containing a sufficient quantity of docetaxel to provide for administration to a subject **[at]** a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said docetaxel remains stable for greater than about 24 hours and less than about 3 days following addition thereto of an aqueous diluent.

160. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[vessel]** container containing a sufficient quantity of taxane to provide for administration to a subject **[at]** a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein refrigeration does not adversely affect the stability of said taxane.

161. (Reiterated) A method according to claim 160, wherein said taxane is paclitaxel.

162. (Reiterated) A method according to claim 160, wherein said taxane is a paclitaxel analog.

163. (Amended) A method for administration of docetaxel to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[vessel]** container containing a sufficient quantity of docetaxel to provide for administration to a subject **[at]** a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein refrigeration does not adversely affect the stability of said docetaxel.

164. (Amended) A method for treatment of primary tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a **[vessel]** container containing a sufficient quantity of taxane to provide for administration to a subject **[at]** a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2.

165. (Amended) A method for treatment of primary tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a **[vessel]** container

containing a sufficient quantity of docetaxel to provide for administration to a subject **[at]** a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2.

166. (Amended) A method for treatment of metastatic tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a **[vessel]** container containing a sufficient quantity of taxane to provide for administration to a subject **[at]** a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2.

167. (Amended) A method for treatment of metastatic tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a **[vessel]** container containing a sufficient quantity of docetaxel to provide for administration to a subject **[at]** a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2.

168. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[vessel]** container containing a sufficient quantity of taxane to provide for administration to a subject **[at]** a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said taxane does not leach plasticizer from administration devices used to administer said unit dosage formulation.

169. (Amended) A method for administration of docetaxel to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[vessel]** container containing a sufficient quantity of docetaxel to provide for administration to a subject **[at]** a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said docetaxel does not leach plasticizer from administration devices used to administer said unit dosage formulation.

170. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[vessel]** container containing a sufficient quantity of taxane to provide for administration to a subject **[at]** a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form confers reduced incidence of hypersensitivity as compared to a subject receiving a formulation containing a cremophor.

171. (Amended) A method for administration of docetaxel to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[vessel]** container containing a sufficient quantity of docetaxel to provide for administration to a subject **[at]** a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form confers reduced incidence of hypersensitivity as compared to a subject receiving a formulation containing a cremophor.